K122348

RECHERCHES TECHNIQUES DENTAIRES

OCT 15 2012

510(k) Summary
[As described in 21CFR 807.92]

1. **Submitter by:**
   RECHERCHES TECHNIQUES DENTAIRES (R.T.D.)
   3 RUE LOUIS NEEL
   TECHNOPARC, ESPACE GAVANIERE
   38120 SAINT EGREVE
   FRANCE 38120
   Phone: 33-4-76565663

2. **Contact Person:**
   Manh Quynh Chu
   R.T.D.
   3 Rue Louis Neel
   St. Egreve, FRANCE 38120
   Phone: 33-4-76565663

3. **Date Prepared: 26-Jul-2012**

4. **Trade Name:**
   Quartz Splint

5. **Common Name:**
   - Dental splinting
   - Tooth shade resin material21

6. **Classification Name:**
   - Dental/Resin, denture, relining, repairing, rebasing (21 CFR 872.3760, Product Code EBI)
   - Material, tooth shade, resin (21 CFR 872.3690, Product Code EBF)

7. **Predicate Device(s):**
   Device: EVERSTICK
   Manufacturer: STICK TECH LTD
   510(k) Number: K011788

   Device: SPLINT-IT
   Manufacturer: PENTRON INC
   510(k) Number: K972985

   Device: RIBBOND
   Manufacturer: RIBBOND Inc

RTD • 3, rue Louis Neel • Technoparc Espace Gavanière • 38120 SAINT-EGREVE • FRANCE ISO 13485 (G-MED)
Tél.: 33(0)4 76 56 56 66 • Fax: 33(0)4 76 56 11 77 • E-mail: infos@rtd.fr • Internet: http://www.rtd.fr
SARL-RCS GRENOBLE B 065 501 055 / APE 331 B / TVA Intra N° FR 44 068 501 055

13. Technological characteristics:

The predicate devices are made of continuous glass fibers/polyethylene fibers. The predicate devices are offered in a dry, non-impregnated fibers or in a light-cured resin impregnated fibers. QUARTZ SPLINT have the same technological characteristics as these predicate devices as they are made of continuous quartz fibers impregnated in a light-cured resin. Polymerization or curing is the same for all these devices with help of halogen or LED dental light system. A flowable nano-hybrid, light-cured composite especially designed for use with the fiber products for the stabilization/splinting of mobile teeth is available. All predicate devices have the same intended use as QUARTZ SPLINT system.

14. Performance

Physical and mechanical properties testing of the subject and predicate devices have been evaluated according to ISO 4049:2009. The testing results indicate that the subject and predicate device comply with the requirements of ISO 4049:2009. Internal and external tests demonstrate that QUARTZ SPLINT system compared to the predicate devices perform as well as equal or better in mechanical features which are the main function for a splint.

Biological evaluation such as cytotoxicity tests (according to ISO 10993-5) has been conducted and results comply with the requirements.

15. Conclusion

In vitro tests and clinical evaluation demonstrate that the QUARTZ SPLINT system (subject device) is substantially equivalent in safety and effectiveness to the predicate device.

RTD - 3, rue Louis Neel - Technoparc Espace Gavanière - 38120 SAINT-EGREVE - FRANCE ISO 13485 (G-MED)
Tél.: 33(0)4 76 56 56 66 - Fax: 33(0)4 76 56 11 77 - E-mail: infos@rtd.fr - Internet: http://www.rtd.fr
SARL-RCS GRENOBLE B 068 501 055 - APE 331 B / TVA Intra N° FR 44 068 501 055

510(k) Number: K913040

Device: EVERSTICK
Manufacturer: STICK TECH LTD
510(k) Number: K031341

8. Description of the Device:

Quartz Splint is made of quartz fibers impregnated a light-cured resin matrix. Quartz Splint is a complete system that contains different structures and it is available in different structures and sizes:
Quartz Splint UD
Quartz Splint WOVEN
Quartz Splint ROPE
Quartz Splint MESH
Quartz Splint Resin/Flow

9. Intended Use:

The splinting system is designed for use in oral splintings or to support laboratory-processes composite bridge/denture work

- QUARTZ SPLINT™ UD (Unidirectional): Composite laboratory bridge strengthening/ reinforcement
- QUARTZ SPLINT™ WOVEN: Direct Splinting/Bridge and Implant positioning reinforcement. Splinting of mobile teeth/temporary stabilization in Clinical use. Retention of teeth subsequent to orthodontic therapy.
- QUARTZ SPLINT™ ROPE: Laboratory splint fabrication for bridge reinforcement or denture repair. Periodontal splinting of mobile teeth in Clinical use.
- QUARTZ SPLINT™ MESH: Denture reinforcement and denture repair.
- QUARTZ SPLINT™ RESIN: for additional wetting during the application of the finished splints
- QS FLOW™: a nano filled, light cured flowable composite designed to be used with the QUARTZ SPLINT system for reinforcement and stabilizing of mobile teeth.

10. Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate device.

11. Non-Clinical Tests:

Verification and validation were conducted to ensure the expected performance of the Quartz Splint system.

12. Clinical Performance Data:

No clinical studies were utilized for the purpose of obtaining safety or effectiveness data.

RTD • 3, rue Louis Neel • Technoparc Espace Gavanière • 38120 SAINT-EGREVE • FRANCE ISO 13485 (G-MED)
Tél.: 33(0)4 76 56 56 66 • Fax: 33(0)4 76 56 11 77 • E-mail: infos@rtd.fr • Internet: http://www.rtd.fr
SARL-RCS GRENOBLE B 068 501 055 / APE 331 B / TVA Intra N° FR 44 068 501 055

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Manh-Quynh Chu
Technical Director
Recherches Techniques Dentaires
3 Rue Louis Neel
St. Egreve, 38120
France

OCT 15 2012

Re: K122348
Trade/Device Name: Quartz Splint System (Quartz Splint UD, Quartz Splint Woven, Quartz Splint Rope, Quartz Splint Mesh, Quartz Splint Resin, and QS Flow)
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI, EBF, EBG
Dated: July 26, 2012
Received: August 3, 2012

Dear Mr. Chu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): To Be Assigned K122348

Device Name: Quartz Splint System

Indications For Use:

The splinting system is designed for use in oral splintings or to support laboratory-processes composite bridge/denture work

- QUARTZ SPLINT™ UD (Unidirectional): Composite laboratory bridge strengthening/ reinforcement
- QUARTZ SPLINT™ WOVEN: Direct Splinting/Bridge and Implant positioning reinforcement. Splinting of mobile teeth/temporary stabilization in Clinical use. Retention of teeth subsequent to orthodontic therapy.
- QUARTZ SPLINT™ ROPE: Laboratory splint fabrication for bridge reinforcement or denture repair. Periodontal splinting of mobile teeth in Clinical use.
- QUARTZ SPLINT™ MESH: Denture reinforcement and denture repair.
- QUARTZ SPLINT™ RESIN: for additional wetting during the application of the finished splints
- QS FLOW™: a nano filled, light cured flowable composite designed to be used with the QUARTZ SPLINT system for reinforcement and stabilizing of mobile teeth.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122348